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DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 24 June 2009 has been entered in full. Claims 1-45, 47, 49-61, 65, 66, 71, and 76 have been cancelled and claims 46, 62, 67, 68, 77, 81, 82, 87, 88, 90, 91, 92, 94, 97, and 98 have been amended. Claims 99-126 have been added.

Claims 46, 48, 62-64, 67-70, 72-75, 77-126 are under examination.

Rejections withdrawn

35 USC § 112, Second paragraph

Applicant's response and arguments filed on 06/24/2009 have overcome the rejection of claims 46, 48, 62-64, 67-70, 72-75, 77-98 under 35 U.S.C. 112, second paragraph.

First, Applicants indicate that a scientist in the field of the invention at the time of filing would have been familiar with the proteins expressed on blood vascular endothelial cells to which these acronyms refer (acronyms used in the rejected claims that include "PAL-E" and "VEGFR-1" and VEGFR-2), and would not have needed the acronyms spelled out in order to give meaning to the claims.

In addition, Applicants have amended claim 46 with the amendment reciting "an effective amount" and, claim 62 with the amendment reciting "where the inhibition of Flt4 function treats breast cancer.".

The rejection of claims 46, 48, 62-64, 67-70, 72-75, 77-98 rejected under 35 U.S.C. 112, second paragraph, has been withdrawn.

Double Patenting

At page 37 of the response, Applicants argue that the preamble of the claim provides antecedent basis for "said mammalian organism" and injects additional life and meaning to the claim in specifying, "A method of inhibiting genesis of blood vessels in a mammalian organism having a disease characterized by expression of Flt4 tyrosine kinase (Flt4) in blood vessels." The purpose recited in the preamble of claim 81, and the mammalian organism to be treated, would not have been obvious from any claim of the '777 patent. (See Jalkanen declaration at paragraphs 7.1.) The claims in the '777 patent are directed to a distinct invention and do not suggest the invention of claim 81. A similar analysis applies to at least claims 82, 94, and 103, for example. See Jalkanen declaration at paragraphs 7.2 and 7.3. In fact, all claims with preambles that are distinct from subject matter claimed in the '777 patent are unobvious in view of the claims of the '777 patent.

In response to applicant's arguments, the recitation of the claim preamble relating to the targeting of blood vessels in claims 62, 77, 81, 82, 94, 103, and 104 has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

However, claims 62, 77, 81, 82, 94, 103, and 104 of the instant application are not rejected under Double Patenting over claims of the '777 patent, because Applicants have amended these claims with limitations reciting "bispecific antibody" or "blood vascular endothelial marker antigen" that are not encompassed by the claims of the '777 patent.

(i). Applicant's response and arguments filed on 06/24/2009 have overcome the double patenting rejection of claims 46, 62, 67, 68, 72, 78, 81, 82, 84-86, 89-92, 94, 96 regarding the

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recitation of "blood vessel (or vascular) endothelial cells" or "blood vessels" over the claims of the '777 patent.

Based on Applicants' arguments provided in the response and orally presented during the interview, it was determined that the the claims reciting "blood vessel (or vascular) endothelial cells" or "blood vessels" are not obvious over the claims of the '777 patent reciting "cells" or "endothelial cells" because the recitation "blood vessel (or vascular) endothelial cells" or "blood vessels" recited in the claims of the instant application requires the expression of a blood vascular endothelial marker antigen including PAL-E, VEGF-R1, and VEGFR-2, that are not encompassed by the endothelial cells in the claims of the '777 patent.

The rejection of claims 46, 62, 67, 68, 72, 78, 81, 82, 84-86, 89-92, 94, 96 with respect to the recitation of "blood vessel (or vascular) endothelial cells" or "blood vessels" rejected under Double Patenting over claims of the '777 patent, has been withdrawn.

(ii). Applicant's response and arguments filed on 06/24/2009 have overcome the double patenting rejection of claims 46, 48, 62, 68, 70, 72-75, 77-80, 82, 86, 90, and 92 regarding the recitation of "bispecific antibodies" over the claims of the '777 patent.

Based on Applicants' arguments provided in the response and orally presented during the interview, it was determined that the instant claims reciting "bispecific antibodies" are not obvious over the claims of the '777 patent reciting " antibodies" because the claims of the instant application require the bispecific antibody to bind to Flt4 as well as a blood vascular endothelial maker expressed on the surface of blood vascular endothelial cells (including PAL-E, VEGF-R1, and VEGFR-2), which are not encompassed in the recitation of antibody recited in the claims of the '777 patent.

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The rejection of claims 46, 48, 62, 68, 70, 72-75, 77-80, 82, 86, 90, and 92 with respect to the recitation of "bispecific antibody" rejected under Double Patenting over claims of the '777 patent, has been withdrawn.

(iii). Applicant's response and arguments filed on 06/24/2009 have overcome the double patenting rejection of claims 64, 67, 68, 87, 89, 91, and 92 regarding the recitation the step comprising screening for a condition characterized by blood vessel expression of Flt4 over the claims of the '777 patent.

Based on Applicants' arguments provided in the response and orally presented during the interview, it was determined that the claims of the instant application reciting the step comprising screening for a condition characterized by blood vessel expression of Flt4 are not obvious over the claims of the '777 patent because the screening step in the claims of the instant requires the specific step of screening to identify a neoplastic disorder characterized by blood vessels that comprise endothelial cells expressing Flt4 (See, e.g., Jalkanen declaration at paragraph 8.4). However, the claims of the '777 patent recite steps for screening a mammalian subject to identify a neoplastic disorder characterized by cells expressing Flt4 receptor tyrosine kinase (Flt4), which do not encompass the endothelial cells recited in the instant claims.

The rejection of claims 64, 67, 68, 87, 89, 91, and 92 with respect to the recitation of the step comprising screening for a condition characterized by blood vessel expression of Flt4 rejected under Double Patenting over claims of the '777 patent has been withdrawn.

New Ground of Rejection

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Claim Rejections - 35 USC § 112 (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The newly added claims 114, 115, and 117 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection. The amended claim represents a departure from originally filed. Although Applicant has pointed out the location for the support for the newly claims 114, 115, and 117 in the specification (see paragraphs [0051], [0058]-[0060] of published application), the examiner has determined that the support is not sufficient. Claim 114 recites “(b) monitoring the progression of the therapy, said monitoring including measuring the quantity or distribution of Flt4 within blood vasculature of the human subject”, claim 115 recites “wherein the monitoring comprises exposing a cell sample from the human subject to an anti-Fit4 antibody or a polypeptide comprising an antigen binding fragment of said anti-Fit4 antibody, and measuring Flt4 by detecting binding of said antibody or polypeptide to Flt4 in the cell sample”, and claim 117 recites “further comprising monitoring the progression of the inhibiting, said monitoring including measuring the quantity or distribution of Flt4 within blood vasculature of the human subject.”

However, the paragraphs [0051] and [0058]-[0060] of the published application do not specifically provide support for the "monitoring" step in recited in claims 114, 115, and 117 of the instant application.

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Conclusion

Claims 114, 115, and 117 are not allowed. Claims 46, 48, 62-64, 67-70, 72-75, 77-113, 116, 118-126 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
October 16, 2009

/Robert Landsman/
Primary Examiner, Art Unit 1647